

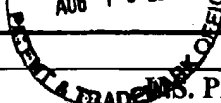
# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 4

AUG 16 2004

Application Number	10/657,045
Filing Date	09/04/03
First Named Inventor	Tedeschi et al.
Group Art Unit	1615
Examiner Name	Fubara, Blessing M.
Attorney Docket Number	P297CON2 (51288-00061US)



## **U.S. PATENT DOCUMENTS**

EXAMINER INITIALS	DOCUMENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
Boe	4,373,009	02/08/83	Winn	428	424.2	
	4,585,666	04/29/86	Lambert	427	2	
	4,625,012	11/25/86	Rizk et al.	528	28	
	4,894,231	01/16/90	Moreau et al.	424	426	
	5,032,666	07/16/91	Hu et al.	528	70	
	5,040,544	08/20/91	Lessar et al.	607	122	
	5,134,192	07/28/92	Feijen et al.	525	54.1	
	5,171,217	12/15/91	March et al.	604	507	
	5,380,299	01/10/95	Fearnot et al.	604	265	
	5,383,928	01/24/95	Scott et al.	623	1.12	
	5,447,724	09/05/95	Heimus et al.	424	426	
	5,464,650	11/07/95	Berg et al.	427	2.3	
	5,470,307	11/28/95	Lindall	604	20	
	5,512,055	04/30/96	Domb et al.	604	265	
	5,525,348	06/11/96	Whitbourne et al.	424	423	
	5,554,182	09/10/96	Dinh et al.	600	36	
	5,562,922	10/08/96	Lambert	424	486	
	5,571,089	11/05/96	Crocker	604	103.01	
	5,591,227	01/07/97	Dinh et al.	623	1.22	
	5,605,696	02/25/97	Eury et al.	424	423	
	5,609,629	03/11/97	Fearnot et al.	623	1.42	
	5,612,052	03/18/97	Shalaby	424	426	
	5,624,411	04/29/97	Tuch	604	265	
	5,637,113	06/10/97	Tartaglia et al.	623	1.42	
	5,645,931	07/08/97	Fan et al.	428	334	
	5,660,873	08/26/97	Nikolaychik et al.	427	2.24	
	5,662,960	09/02/97	Hostettler et al.	427	2.3	
	5,674,192	10/07/97	Sahatjian et al.	604	28	
	5,683,451	11/04/97	Lenker et al.	623	1.11	
	5,698,738	12/16/97	Garfield et al.	564	112	
	5,700,286	12/23/97	Tartaglia et al.	623	1.15	
	5,702,754	12/30/97	Zhong	427	2.12	
	5,705,583	01/06/98	Bowers et al.	526	277	
	5,756,145	05/26/98	Darouiche	427	2.24	
Boe	5,756,553	05/26/98	Iguchi et al.	514	772.3	

EXAMINER SIGNATURE	Blessing Fubara	DATE CONSIDERED	10-31-04
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Sheet 2 of 4

Application Number	10/657,045
Filing Date	09/04/03
First Named Inventor	Tedeschi et al.
Group Art Unit	1615
Examiner Name	Fubara, Blessing M.
Attorney Docket Number	P297CON2 (51288-00061US)

5,762,944	06/09/98	Inoue et al.	424	400
5,770,229	06/23/98	Tanihara et al.	424	488
5,776,611	07/07/98	Elton et al.	428	423.1
5,792,106	08/11/98	Mische	604	103.01
5,797,887	08/25/98	Rosen et al.	604	265
5,824,049	10/20/98	Ragheb et al.	623	1.44
5,824,054	10/20/98	Khosravi et al.	623	1.44
5,843,120	12/01/98	Israel et al.	523	1.15
5,843,166	12/01/98	Lentz et al.	623	1.13
5,843,172	12/01/98	Yan	623	1.42
5,849,368	12/15/98	Hostettler et al.	427	536
5,853,745	12/29/98	Darouiche	424	423
5,869,127	02/09/99	Zhong	427	2.12
5,873,904	02/23/99	Ragheb et al.	623	1.13
5,891,108	04/06/99	Leone et al.	604	264
5,900,246	05/04/99	Lambert	424	429
5,919,570	07/06/99	Hostettler et al.	428	424.8
5,972,027	10/26/99	Johnson	623	1.42
5,997,517	12/07/99	Whitebourne	604	265
6,024,763	02/15/00	Lenker et al.	606	191
6,048,360	04/11/00	Khosravi et al.	623	1.11
6,090,901	07/18/00	Bowers et al.	526	277
6,096,070	08/01/00	Ragheb et al.	623	1.39
6,153,252	11/28/00	Hossainy et al.	427	2.3
6,156,345	12/05/00	Chudzik et al.	424	485
6,197,051	03/06/01	Zhong	623	1.46
6,214,901	04/10/01	Chudzik et al.	523	113
6,254,632	07/03/01	Wu et al.	623	1.15
6,258,121	07/10/01	Yang et al.	623	1.46
6,287,285	09/11/01	Michal et al.	604	264
6,299,604	10/09/01	Ragheb et al.	604	265
6,306,176	10/23/01	Whitbourne	623	23.59
6,344,035	02/05/02	Chudzik et al.	604	265
6,355,060	03/12/02	Lenker et al.	623	1.34
6,379,382	04/30/02	Yang	623	1.42
6,451,050	09/17/02	Rudakov et al.	623	1.15
6,451,373	09/17/02	Hossainy et al.	427	2.25

EXAMINER SIGNATURE	<i>Blessing Fubara</i>	DATE CONSIDERED	10-31-04
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Sheet 3 of 4

Application Number	10/657,045
Filing Date	09/04/03
First Named Inventor	Tedeschi et al.
Group Art Unit	1615
Examiner Name	Fubara, Blessing M.
Attorney Docket Number	P297CON2 (51288-00061US)

BF	6,458,152	10/01/02	Khosravi et al.	623	1.13	
	6,488,701	12/03/02	Nolting et al.	623	1.13	
	6,506,437	01/14/03	Harish et al.	427	2.25	
BF	6,547,814	04/15/03	Edwin et al.	623	1.13	

## **FOREIGN PATENT DOCUMENTS**

EXAMINER INITIALS	DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
BF	357401B1	3/90	EP			X	
BF	352295 B1	6/93	EP			X	
BF	397784 B1	10/93	EP			X	

## **OTHER DOCUMENTS**

EXAMINER INITIALS	Include name of the author (in CAPITAL LETTERS), title of the article, title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
BF	Adams et al., "Inhibition of Nitric Oxide Synthase Disrupts Inhibitory Gating of Auditory Responses in Rat Hippocampus," The Journal of Pharmacology and Experimental Therapeutics, 287:760-5 (November 1998)
	Berkenbosch et al., "Management of Postoperative Chylothorax with Nitric Oxide: A Case Report," Critical Care Medicine, 27:1022-4 (May 1999)
	Carrier et al., "Nitric Oxide Inhalation in the Treatment of Primary Graft Failure Following Heart Transplantation," The Journal of Heart and Lung Transplantation, 18:664-7 (July 1999)
	Cooper et al., "Transient Loss of Resistance to Pulmonary Tuberculosis in p47PHOX-/-Mice," Infection and Immunity, 68:1231-4 (March 2000)
	El-Haddad et al., "Nitric Oxide Modulates Spontaneous Swallowing Behaviour in Near-Term Ovine Fetus," American Journal of Physiology, 277:R981-6 (October 1999)
	Freedman, et al., "Acute Effect of Nitric Oxide on Raynaud's Phenomenon in Scleroderma," The Lancet, 354:739 (August 1999)
	Goodwin et al., "Favorable Response of Eisenmenger Syndrome to Inhaled Nitric Oxide During Pregnancy," American Journal of Obstetrics and Gynecology, 180:64-7 (January 1999)
	Gradini et al., "Nitric Oxide Synthases in Normal and Benign Hyperplastic Human Prostate: Immunohistochemistry and Molecular Biology," Journal of Pathology, 189:224-9 (October 1999)
	Holopainen et al., "Nitric Oxide Inhalation Inhibits Pulmonary Apoptosis but not Inflammatory Injury in Porcine Meconium Aspiration," Acta Paediatrica, 88:1147-55 (October 1999)
BF	Ishihara et al., "Inhaled Nitric Oxide Prevents Left Ventricular Impairment During Endotoxemia," Journal of Applied Physiology, 85:2018-24 (December 1998)

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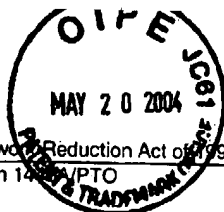
Sheet 4 of 4

Application Number	10/657,045
Filing Date	09/04/03
First Named Inventor	Tedeschi et al.
Group Art Unit	1615
Examiner Name	Fubara, Blessing M.
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BF	Jacobs et al., "Aerosolized Soluble Nitric Oxide Donor Improves Oxygenation and Pulmonary Hypertension in Acute Lung Injury," American Journal of Respiratory and Critical Care Medicine, 158:1536-42 (November 1998)
	Kiris et al., "Reversal of Cerebral Vasospasm by the Nitric Oxide Donor SNAP in an Experimental Model of Subarachnoid Haemorrhage," Acta Neurochirurgica, 141:1323-9 (1999)
	Lambermont et al., "Effects of Inhaled Nitric Oxide on Pulmonary Hemodynamics in a Porcine Model of Endotoxin Shock," Critical Care Medicine, 27:1953-7 (September 1999)
	Lewis et al., "Nitric Acid Limits the Eicosanoid-Dependant Bronchoconstriction and Hypotension Induced By Endothelin-1 in the Guinea Pig," British Journal of Pharmacology, 126:93-102 (January 1999)
	Payen, et al., "Inhaled Nitric Oxide, Almitrine Infusion, or Their Coadministration as a Treatment of Severe Hypoxemic Focal Lung Lesions," Anesthesiology, 89:1157-65 (November 1998)
	Samama et al., "Inhibition of Nitric Oxide Synthase Impairs Early Olfactory Associative Learning in Newborn Rats," Neurobiology of Learning and Memory, 71:219-31 (March 1999)
BF	Sullivan et al., "Nitric Oxide Successfully used to treat Acute Chest Syndrome of Sickle Cell Disease in a Young Adolescent," Critical Care Medicine, 27:2563-8 (November 1999)

EXAMINER SIGNATURE	Blessing Fubara	DATE CONSIDERED	10-31-04
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet

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of

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Application Number	10/657,045
Filing Date	09/04/2003
First Named Inventor	Fitzhugh et al.
Group Art Unit	1616
Examiner Name	
Attorney Docket Number	14364-0108

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
bf	1	US - 4,954,526	09-04-1990	Keefer	
	2	US - 5,039,705	08-13-1991	Keefer et al.	
	3	US - 5,155,137	10-13-1992	Keefer et al.	
	4	US - 5,171,217	12-15-1992	March et al.	
	5	US - 5,212,204	05-18-1993	Keefer et al.	
	6	US - 5,229,172	07-20-1993	Cahalan et al.	
	7	US - 5,250,550	10-05-1993	Keefer et al.	
	8	US - 5,268,465	12-07-1993	Bredt et al.	
	9	US - 5,366,997	11-22-1994	Keefer et al.	
	10	US - 5,380,758	01-10-1995	Stamler et al.	
	11	US - 5,405,919	04-11-1995	Keefer et al.	
	12	US - 5,428,070	06-27-1995	Cooke et al.	
	13	US - 5,468,630	11-21-1995	Billiar et al.	
	14	US - 5,482,925	01-09-1996	Hutsell	
	15	US - 5,519,020	05-21-1996	Smith et al.	
	16	US - 5,525,357	06-11-1996	Keefer et al.	
	17	US - 5,574,068	11-12-1996	Stamler et al.	
	18	US - 5,583,101	12-10-1996	Stamler et al.	
	19	US - 5,632,981	05-27-1997	Saavedra et al.	
	20	US - 5,650,447	07-22-1997	Keefer et al.	
	21	US - 5,658,565	08-19-1997	Billar et al.	
	22	US - 5,676,963	10-14-1997	Keefer et al.	
	23	US - 5,683,668	11-04-1997	Hrabie et al.	
	24	US - 5,691,423	11-25-1997	Smith et al.	
	25	US - 5,700,830	12-23-1997	Korthuis et al.	
	26	US - 5,714,511	02-03-1998	Saavedra et al.	
	27	US - 5,718,892	02-17-1998	Keefer et al.	
	28	US - 5,721,365	02-24-1998	Keefer et al.	
	29	US - 5,770,645	06-23-1998	Stamler et al.	
	30	US - 5,789,447	08-04-1998	Wink, Jr. et al.	
	31	US - 5,814,656	09-29-1998	Saavedra et al.	
	32	US - 5,814,667	09-29-1998	Mitchell et al.	
	33	US - 5,837,736	11-17-1998	Mitchell et al.	
	34	US - 5,837,313	11-17-1998	Ding et al.	

Examiner  
Signature

Blessing Fabara

Date  
Considered

10-31-04

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Sheet

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of

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Application Number	10/657,045
Filing Date	09/04/2003
First Named Inventor	Fitzhugh et al.
Group Art Unit	1616
Examiner Name	
Attorney Docket Number	14364-0108

## U.S. PATENT DOCUMENTS

U.S. PATENT DOCUMENTS						
Examiner Initials	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		Number-Kind Code <sup>2</sup> (if known)				
Bf	35	US - 5,840,759	11-24-1998	Mitchell et al.		
	36	US - 5,877,216	03-02-1999	Place et al.		
	37	US - 5,891,459	04-06-1999	Cooke et al.		
	38	US - 5,910,316	06-08-1999	Keefer et al.		
	39	US - 5,945,452	08-31-1999	Cooke et al.		
	40	US - 5,958,427	09-28-1999	Salzman et al.		
	41	US - 5,962,520	10-05-1999	Smith et al.		
	42	US - 5,994,444	11-30-1999	Trescony et al.		
Bf	43	US - 6,024,918	02-15-2000	Hendriks et al.		

## FOREIGN PATENT DOCUMENTS

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
Bf		WO	00/02501		William Harvey Research LTD.	01-20-2000		
Bf		WO	0030658	A1	Smith et al.	06-02-2000		

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
Bf		Keefer, et al; "NONOates" (1-Substituted Diazen-1-ium-1,2-diolates) as Nitric Oxide Donors: "Convenient Nitric Oxide Dosage Forms." Methods in Enzymology, Vol 268: 281-293	
		Saavedra, et al.; Conversion of Polysaccharide to Nitric Oxide-Releasing Form Dual-Mechanism Anticoagulant Activity of Diazeniumdiolates Heparin." Bioorganic & Medicinal Chemistry Letters 10 (2000) 1-3	
		Hrabie, et al; "New Nitric Oxide-Releasing Zwitterions Derived from Polyamines." J.Org. Chem. 1993, 58 1472-1476	
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Examiner Signature	Blessing Eubank	Date Considered	10-31-04
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Sheet	3	of	3	Application Number	10/657,045
				Filing Date	09/04/2003
				First Named Inventor	Fitzhugh et al.
				Group Art Unit	1616
				Examiner Name	
				Attorney Docket Number	14364-0108

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